Jul 19 04 09:25a Kimberly Moses 513-337-1919 p.5

Application No. 10/021,407 Office Action dated: Feb 18, 2004

REMARKS/ARGUMENTS

Claims 5-8, 13, and 14 are rejected under 35 USC 112. Claims 5-8 and 13,14 are rejected under 35 USC 1036 are rejected as anticipated. Claims 5 and 14 are amended. Claims 15-18 are added. Claims 5-8, 13, 14, and 15-18 remain pending.

Added Claims:

Claims 15-18 are added. Support for Claim 15 which includes recital of a cutter lumen and a vacuum lumen is found in the drawings and at page 6, lines 10-15. No new matter is added.

112 Rejection:

Claims 5-8, 13 and 14 are rejected under 35 USC 112 first paragraph as failing to comply with the written description requirement. The Examiner objects to the description of the material being "spaced longitudinally from said port of said needle.", stating the specification does not support such a claim.

It is respectfully urged that the specification and drawings illustrate the material is spaced longitudinally from the port, and that the language in the specification regarding orientation of the needle is not inconsistent with the claim language. For instance, see Figure 2 which shows the port 36 and the tip 60, with the tip 60 being spaced longitudinally from the port. However, in order to more clearly point out the position of the material, the claims have been amended to recite the material is spaced distally from the side port of the needle. Note that this is supported by the drawings and specification which disclose the material in a cavity in the pointed tip, where the pointed tip is positioned at the distal tip of the needle (and so the cavity and the material is disposed distally of the side port of the needle).

p.6

Application No. 10/021,407 Office Action dated: Feb 18, 2004

103 Rejection

Jul 19 04 09:25a

Claims 5-8 are rejected as obvious over Publication 2003/0040671 in view of US Patent 5,782,764. This rejection is improper for at least the following reasons.

First, it is respectfully urged that the Examiner has mischaracterized the art cited above. The Examiner states that the Somogyi et al. art discloses a biopsy device (Figure 7A) with a tubular needle (701). It is respectfully urged that the device 701 is a tube, and not a needle as the Examiner has characterized the device 701. The reference at page 2, paragraph 23 lists items included in the definition of "medical tube", and the list does not appear to include a needle. Accordingly, the Examiner is respectfully requested to clarify how the Somogyi et al. reference teaches or suggests a needle.

Second, the Examiner has not provided any motivation for modifying Somogyi et al. The Examiner admits that Somogyi et al. does not disclose a needle formed of a nonmetallic material, or having a sharpened tip. The Examiner then goes on to conclude it would be obvious to modify the Somogyi et al. device to better penetrate tissue and to not distort an MRI image. However, the Examiner has not pointed to any reason why one using the tube of Somogyi would want or desire either 1) a sharpened tip, or 2) to image using MRI.

Third, it is not clear that Somogyi et al. would be operable with MRI. Somogyi et al. teaches the use of a magnet with a medical tube. It is respectfully urged that it is not clear how such a tube with a magnet would be suitable for use with MRI. (In other words, the Examiner is asked to explain why this magnet would not distort the MRI image.

Fourth, even if one combined the references as suggested by the Examiner, the resulting combination would not teach all the limitations of the claims. In particular, the resulting combination would not teach the following:

- 1. a distal tip having a hollow cavity;
- 2. material in the cavity; and

Application No. 10/021,407 Office Action dated: Feb 18, 2004

3. the material spaced distally from said side port of said needle.

Note that the Werner patent does appear to show a hollow cavity in a distal tip, and that the agent 46 is not positioned distally of the recess 48. The Examiner states that Somogyi et al. discloses a closed distal tip having a hollow cavity partially filled with a material 703, but it is respectfully urged that Somogyi et al. describes 703 as being a magnet, not as being a hollow cavity.

The Examiner is also requested to to consider the Golden patent 5,425,382 cited in Somogyi et al. as an exemplary method for detecting a magnet in the body. It is respectfully urged that Somogyi et al. is not directed to devices for use with MRI, but instead teaches away from the use of imaging devices, and instead seeks to detect the location of magnetic materials using non imaging devices, such as shown in Golden '382.

Claims 5,13, and 14 are rejected as obvious over Somogyi et al. in view of 2002/0082519. It is respectfully urged that this rejection is improper for all the reasons set forth above with respect to Somogyi et al.

Respectfully submitted,

Gerry Gressel, Esq. Reg. No. 34,342

Attorney for Applicant(s)

Johnson & Johnson One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003 (513) 337-3535 Date: July 19, 2004